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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/740,824

Applicant(s)

QUANZ ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 2-2-04, 3-15-04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9-23, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-23, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

The amendments of February 2, 2004, and March 15, 2004, have been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 9-23, 25 and 26 are pending and are examined on the merits.

***Claim Rejections - 35 USC § 112***

Claims 14, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitations "a purity, in U/ $\mu$ g of purified protein, of at least 80%", "a purity, in U/ $\mu$ g of purified protein, of at least 90%" and "a purity, in U/ $\mu$ g of purified protein, of at least 95%", in claims 14, 25 and 26 as amended are indefinite because it is not clear how pure the enzyme must be.

It is noted that the amended claims recite the purity in terms of specific activity, and that this activity can be compared to the specific activity of pure amylosucrase. However, as pointed out in the advisory action of February 13, 2003, it is not clear that the specific activity of "pure"

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amylosucrase is "known." Moreover, applicant has not established for the record what the specific activity of pure amylosucrase is, nor has applicant established whether there is in fact a single art-recognized specific activity for pure amylosucrase. Thus, while the claims as amended now recite the enzyme purity in terms of an ascertainable parameter, the claims as amended still fail to provide a benchmark, i.e. 100% purity, on which the claimed partial percentages are based. Rejection under § 112, second paragraph, remains required.

All of applicant's argument regarding this ground of rejection has been fully considered, but is not persuasive of error. Applicant is correct in the assertion that the claimed units (U/ $\mu$ g protein) would provide an adequate basis for comparing enzyme preparations of unknown purity with homogeneous amylosucrase. However, applicant simply has not established for the record what the activity of "pure" or homogeneous amylosucrase actually is. For example, if applicant established for the record that "pure" amylosucrase had an activity of 100 activity units per microgram of protein, then a practitioner would know that a preparation having 80 activity units per microgram of protein would be 80% pure. On the current record, applicant still has not established what would constitute 100% pure, so as to provide a baseline such that fractional purities

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can be determined. Absent the 100% pure guideline, fractional purities are essentially meaningless.

It is noted that the Remaud-Simeon reference discloses a specific activity of 0.3 U/mg for one of the enzyme preparations produced therein, which equates to 300 units per  $\mu$ g of protein, using the units recited in applicant's claims. See page 316. However, it is not clear on the current record whether applicant asserts this to be the specific activity of "pure" amylosucrase. Absent of clear guidance on this issue, the claims must be considered indefinite. Note that Remaud-Simeon's definition of an activity "unit" is not sufficient to determine purity, without a disclosure of how much enzyme is responsibility for that activity.

***Claim Rejections - 35 USC § 103***

Claims 9-15, 20-23, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kossman (WO 95/31553) in view of Okada et al (J. Biol. Chem. 249(1):126-135 (1974)) (cited by applicant as reference "AW2" in the information disclosure statement filed December 21, 2000).

Kossman discloses a process of preparing insoluble polysaccharides by contacting sucrose with an amylosucrase under aqueous conditions. See p. 24. Kossman discloses that the

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enzyme should be obtained from the claimed microorganism, *Neisseria polysaccharea* (see p. 5), can be produced recombinantly (see p. 11), can be used in purified form (see p. 24), and can be used in immobilized form (see p. 25). Thus, Kossman differs from the cited claims in that Kossman does not employ the enzyme under buffer-free conditions.

However, Kossman clearly discloses that the enzyme is useful at neutral conditions. See Example 4 at page 35, wherein the enzyme is employed at pH 6.5. Thus, the artisan of ordinary skill, recognizing from Kossman that the enzyme is active at neutral conditions which do not require the addition of a buffer, clearly would have motivated to have omitted the step of adding a buffer to the reaction medium disclosed by Kossman. By omitting the addition of buffer, the artisan of ordinary skill would have made the process easier by omitting a step, and also would have made the process cheaper by omitting the expense of a buffer. Further still, the artisan of ordinary skill clearly had a reasonable expectation that the process would work in the absence of a buffer, based on the fact that the Kossman discloses the enzyme as functioning at neutral conditions.

Kossman also differs from the claims as amended in that Kossman does not disclose that 70% of the sucrose is converted to  $\alpha$ -1,4-glucans and fructose within 23.5 hours. However, Okada

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clearly discloses that the claimed enzyme produces an 80% conversion within 2 hours, a time much shorter than that recited in the claims, under the conditions assayed therein. See Fig. 2, page 128, top of right hand column. Thus, the artisan of ordinary skill clearly would have reasonably expected Kossman's process to have yielded a similar conversion, even in the absence of a buffer. In this regard note again that Kossman discloses that the enzyme is active at neutral conditions, and that there is nothing in either Kossman or Okada suggesting that omission of buffer would lower enzyme efficiency. A holding of obviousness is therefore required.

Claims 9-23, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kossman (WO 95/31553) in view of Okada et al (J. Biol. Chem. 249(1):126-135 (1974)), as applied to claims 9-15, 20-23, 25 and 26 above, and further in view of Remaud-Simeon (Carbohydrate Bioengineering 1995:313-320).

As discussed above, Kossman renders obvious the process recited in claims 9-15, 20-23, 25 and 26. Kossman differs from the claims in that Kossman does not disclose the addition of a polysaccharide acceptor which may be dextrin, glycogen or amylopectin, as recited in claims 16-19. However, Remaud-Simeon clearly discloses that glycogen, starch (which contains

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amylopectin) and maltooligosaccharides act to activate amylosucrase when they are added to the reaction medium. Thus, the artisan of ordinary skill clearly would have been motivated to have added glycogen and amylopectin to the reaction medium to have afforded the activating effect disclosed by Remaud-Simeon. Moreover, in view of the fact that dextrans are very similar chemically to the compounds disclosed by Remaud-Simeon as having an activating effect on amylosucrase, the artisan of ordinary skill clearly would have had a reasonable expectation that dextrans would have had the same activating effect on amylosucrase as glycogen, starch (which contains amylopectin) and maltooligosaccharides. The artisan of ordinary skill would therefore have been motivated to have added dextrin to the reaction medium used for the production of glucans by amylosucrase, as recited in claims 16-19. A holding of obviousness is therefore clearly required.

All of applicant's argument regarding the obviousness rejections has been fully considered but is not persuasive of error. With respect to the omission of buffer resulting in an improvement with respect to product purity due to not having to separate the buffer from the product, one of ordinary skill clearly would have recognized that omitting buffer from the



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prior art process would have meant that the buffer need not have been separated from the product. This advantage therefore cannot be considered unexpected.

With respect to the fact that buffers are used to maintain a pH range during an enzymatic reaction so that the pH does not move outside the enzyme's optimal pH, applicant does not point to any fact suggesting that the amylosucrase reaction in Kossman would have been considered likely to have moved outside the optimal pH of amylosucrase. While other investigators including the Okada, Mackenzie, Tao, Albenne and Remaud-Simeon publications cited by applicant in fact use buffers, there is nothing to indicate that the amylosucrase reaction would not work in the absence of a buffer. Rather, the fact that Kossman's amylosucrase functions at a neutral pH suggests that no buffer would be required. Applicant simply has not provided any evidence suggesting that the pH of Kossman's reaction milieu would tend to change over time such that one of ordinary skill would not have expected the enzyme to function as desired by Kossman.

With respect to a reasonable expectation of success, applicant's attention is directed to the fact that the claimed conversion rate, 70% in 23.5 hours, is relatively low when compared to the conversion rate disclosed in the Okada

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reference, 80% conversion within 2 hours. Thus, even if one of ordinary skill would have expected a lowered conversion rate by performing Kossman's amylosucrase reaction in the absence of a buffer, the lowered conversion rate expected by the artisan of ordinary skill is expressly encompassed by applicant's claims.

With respect to the issue of motivation, or the argued lack thereof, by omitting the addition of buffer, the artisan of ordinary skill would have made the process easier by omitting a step, and also would have made the process cheaper by omitting the expense of a buffer, as discussed above. While applicant urges that this motivation is not expressly stated in the prior art, it is respectfully pointed out that it is well established that sound scientific reasoning may be used to demonstrate obviousness. See *Ex parte Levengood*, 28 USPQ2d 1300 (1993), at 1301. ("Motivation for combining the references need not be explicitly found in the references themselves. Indeed, the examiner may provide an explanation based on logic and sound scientific reasoning that will support a holding of obviousness.") (Citations omitted.)

Moreover, the idea that omission of an unrequired step is *prima facie* obvious is itself well established in the law. See MPEP § 2144.04, subsection "II" and the cases cited therein. In the instant case, all of the prior art of record, including that

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cited in the rejection, make it clear that the enzyme functions optimally at neutral pH. Knowing that the enzyme functioned at neutral pH, and also recognizing that the process of Kossman would not have generated any pH-changing species, the artisan of ordinary skill would have recognized that a buffer would not have been required in Kossman's process, and would therefore have been motivated to have eliminated the buffer from Kossman's process, thereby eliminating the expense of the buffer as well as the time and effort required in preparing the buffered milieu of Kossman. Even conceding that a lowered conversion rate would have been expected in the absence of a buffer, as discussed above, the claimed conversion rate of 70% in 23.5 hours is so much lower than the enzyme's disclosed conversion rate of 80% in 2 hours by the cited Okada publication, that the level of success recited in the claims clearly would have been reasonably expected by one of ordinary skill. Contrary to applicant's argument, none of this is based on hindsight reasoning. Rather, all of the claimed subject matter is what is suggested by the prior art, viewing the disclosures of the various references.

No claims are allowed.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP